



Foreign Agricultural Service

**GAIN Report**

Global Agriculture Information Network

Voluntary Report - public distribution

Date: 6/20/2001

GAIN Report #RS1018

## **Russian Federation**

# **Food and Agricultural Import Regulations and Standards**

## **Registration Procedures for New Food Products**

### **2001**

Approved by:

**Geoffrey W. Wiggin**

**U.S. Embassy, Moscow**

Prepared by:

Margaret Thursland and Mikhail Maximenko

---

### **Report Highlights:**

The Russian Ministry of Health issued a resolution approving the procedure for registration of new products, the form of the certificate of registration, the form of application for state registration of new food products, and the list of new food products subject to state registration.

---

Includes PSD changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Moscow [RS1], RS

In pursuance of the Federal Law "On Quality and Safety of Food Products" and in accordance with the resolution of the Government of the Russian Federation "On State Registration of New Food Products, Materials and Articles" No. 88 of 21 December 2000, Russian Ministry of Health issued a resolution approving the procedure for state registration of new products, the form of the certificate of registration, the form of application for state registration of new food products, and the list of new food products subject to state registration. The resolution was published in Rosiiskaya Gazeta, April 3, 2001.

## DECREE OF THE HEALTH MINISTRY OF THE RUSSIAN FEDERATION

No. 89 of 26 March 2001, Moscow

Registered with the Justice Ministry of the Russian Federation / Registration No. 2639

**ON STATE REGISTRATION OF NEW FOOD PRODUCTS, MATERIALS AND ARTICLES, PERFUMES AND COSMETIC PRODUCTS, PRODUCTS FOR DENTAL CARE, TOBACCO PRODUCTS**

In pursuance of the Federal Law "On quality and safety of food products" and in accordance with the resolution of the Government of the Russian Federation "On state registration of new food products, materials and articles" No. 988 of 21 December 2000, I decree:

1. To approve:
  - 1.1. the procedure for state registration of new products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products (Appendix 1).
  - 1.2. the form of the Certificate of registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products (Appendix 2).
  - 1.3. the form of application for state registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products (Appendix 3).
  - 1.4. the Nomenclature (List) of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products that are subject to state registration (Appendix 4).
2. To charge the Department of state sanitary and epidemiological control of the Health Ministry of Russia with the task of state registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products.

The Department of state sanitary and epidemiological control is obliged:

- 2.1. to organize, beginning from 1 April 2001, the conduct of state registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products in accordance with the regulation approved by the resolution of the Government of the Russian Federation of 21 December 2000 "On state registration of new food products, materials and articles" and the procedure approved by par. 1.1 of this decree.
- 2.2. to ensure the maintenance of the State Register of food products, materials and articles allowed to be manufactured in the Russian Federation or imported into the Russian Federation for sale; with respect to products of animal origin - together with the Ministry of agriculture of the Russian Federation.
- 2.3. by 1 April 2001 to make the necessary changes and addenda to the normative (regulatory) documents.

3. The Department for development and economics of public health protection, the Department of state sanitary and epidemiological control are obliged, by 1 April 2001, to prepare together with the Ministry of agriculture and in consultations with the Finance Ministry of Russia a "Procedure of payment for state registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products" and to submit it for approval in accordance with established procedure.
4. The Center for standardization and certification of the Health Ministry of Russia is obliged to ensure:
  - 4.1. the production of state registration certificate forms for state registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products, having the specified degree of protection against counterfeiting.
  - 4.2. the implementation of organizational and technical measures in connection with state registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products in accordance with the approved nomenclature.
  - 4.3. the conduct of expert examinations related to state registration of new food products, materials and articles, perfumes and cosmetic products, products for dental care, tobacco products with the involvement, on a contractual basis, of accredited organizations and experts.
5. The Federal Center for state sanitary and epidemiological control of the Health Ministry of Russia is obliged to ensure the implementation of organizational and technical measures in connection with state registration of biologically active supplements and tobacco products in accordance with the approved nomenclature.
6. The supervision over the fulfillment of this decree shall be the responsibility of the first deputy minister of health of the Russian Federation, G.G. Onischenko.

U. Shevchenko  
Minister

**Procedure of state registration of new food products, materials and articles, perfumes and cosmetic products, products and articles for dental care, tobacco products**

1. State registration of food production, materials and articles, perfumes and cosmetic products, products and articles for dental care, tobacco products is carried out in accordance with the Regulation on state registration of new food products, materials and products approved by the resolution of the Government of the Russian Federation No. 988 of 21 December 2000 and by this decree.
2. State registration is carried out at the expense of the applicant in accordance with established procedure.
3. In order to obtain state registration of its product the applicant (an individual entrepreneur or an organization that develops and/or prepares a Russian product or imports foreign-made products) is required to submit to the Department of state sanitary and epidemiological control of the Health Ministry of Russia, to the Federal Center for state sanitary and epidemiological control of the Health Ministry of Russia an application of a standard form and a set of documents certified in accordance with established procedure:

For products made in Russia:

- normative (regulatory) and/or technical documents (standards, technical specifications, rules, technological instructions, etc.) approved in accordance with established procedure;
- a copy of the sanitary and epidemiological conclusion on the compliance of technical documents (with the existing requirements) (accounting form No. 303-00-1/u);
- a copy of the sanitary and epidemiological conclusion with respect to the new product; a product imported into the Russian Federation (accounting form No. 303-00-3/u) or a copy of the sanitary-epidemiological conclusion with respect to a product that presents a potential threat to human life and health (accounting form No. 303-00-7/u);
- a document confirming the payment by the applicant of a duty for the consideration of its application for state registration of the product;

For products imported into Russia:

- specifications;
  - copies of documents issued by competent authorities of the country of the product's origin confirming that the product is safe for human life and health;
  - a document confirming the payment by the applicant of a duty for the consideration of the application for the registration of the product.
4. If necessary, organizations and experts accredited with the Health Ministry of Russia may be involved on a contractual basis in the conduct of expert examinations (checking the conditions in which the sample product was made for compliance with the requirements set out in the technical documentation).
  5. The registration certificate must be issued within five days of the submission by the applicant of the document confirming the payment for the state registration of the product.

6. A refusal to effect the state registration of a product can be appealed against in accordance with established legal procedure.
7. State registration certificates must be issued on standard forms having the corresponding degree of protection against counterfeiting.

Appendix 3

**Application for the conduct of state registration of new food products, materials and articles, perfumes and cosmetic products, means and products for dental care, tobacco products**

To: (name of the state sanitary and epidemiological control service) \_\_\_\_\_

\_\_\_\_\_  
(Name and legal address of the organization; full name, data of the identity document of the individual entrepreneur who develops and prepares a Russian product)

represented by (full name of the director) \_\_\_\_\_

requests to carry out the state registration of \_\_\_\_\_  
(name of product indicating also the trade mark, if any)

Applicant

\_\_\_\_\_ (signature, full name, seal)

Application was accepted on (date) and entered into the register under No. \_\_\_\_\_

## Appendix 2

Health Ministry of the Russian Federation  
Chief sanitary-epidemiological service of the Russian Federation  
Chief state sanitary physician of the Russian Federation

**Certificate****Of state registration of new food products, materials and articles, perfumes and cosmetic products, means and articles for dental care, tobacco products****No.****Date:**

This certificate is issued to (name and legal address of the organization, full name, identity document data of individual entrepreneur that develops and prepares a Russian product)

---

In accordance with Federal Law No. 29-FZ of 2 January 2000 "On quality and safety of food products", the product (name of the product and its trade mark, if any) \_\_\_\_\_

Code in the List of Products for Foreign Trade Activities (TNVD code)(OKP)

Has been subjected to registration procedures and entered into the State register of food products, materials and articles allowed for production in the Russian Federation or for importation into the Russian Federation and for sale.

Normative (Regulatory) or technical documents under which the product is produced:

---

---

Hazardous properties of the product and specification of their parameters  
(Hygienic characteristic of the product)

Field of application

Safety measures which are required to be observed in the production, sale and consumption (use) of the product \_\_\_\_\_

Chief State Sanitary Physician

(Deputy Chief State Physician)





**NOMENCLATURE (LIST) OF NEW FOOD PRODUCTS, MATERIALS AND ARTICLES, PERFUMES AND COSMETIC PRODUCTS, MEANS AND PRODUCTS FOR DENTAL CARE, TOBACCO PRODUCTS**

1. Mineral water:
  - natural potable, therapeutic potable water;
  - bottled potable water
4. Child's nutrition products:
  - canned fruit and vegetables, including homogenized canned vegetables, including sterilized;
  - canned fruits;
  - woman's milk substitutes;
  - additional food-stuffs (on the basis of cereals, cereals and milk, fruit and vegetables, meat, fish, meat and vegetable and fish and vegetable);
  - food-stuffs for feeding prematurely born children;
  - herbal tea for children;
  - special food-stuffs for pregnant and nursing women;
12. Dietetic food-stuffs (medicinal and prophylactic);
  - dietetic and diabetic bread and bread products;
  - dietetic and diabetic confections;
  - alcohol free drinks, dietetic;
  - animal oils, vegetable oils, margarines (artificial butter) for dietetic nutrition;
  - dietetic canned fruit and vegetables;
  - canned foods enriched with macro- and micro-nutrients;
  - specialized mono- and poly-component food-stuffs for controlling and reducing body weight, including food-stuffs for athletes;
  - food-stuffs for enteric nutrition.
4. Milk products enriched with macro- and micro-nutrients.
5. Food supplements:
  - canned food supplements;
  - anti-oxidants;
  - bread modifiers;
  - anti-caking substances;
  - emulsifiers;
  - soluble salts;
  - gelling agents;
  - stabilizers;
  - densifiers;
  - foam agents;
  - anti-foaming additives;
  - water-retaining agents;

- baking powders;
  - solvents-oestrogens;
  - solvents-carriers;
  - fillings;
  - gas-packing agents;
  - acid regulators;
  - acids;
  - dye-stuffs;
  - sweeteners;
  - taste and aroma intensifiers;
  - icing;
  - aromatic bases;
  - aromatic mixtures;
  - essences;
  - compositions of aromatic substances/for nutrition purposes;
  - fermenting preparations;
  - sorbents;
  - flocculators;
  - coagulators;
  - ion-exchange materials;
  - membranes;
  - filtering materials;
  - catalysts;
  - starting cultures, bacterial ferments;
  - complex pre-mixes for industrial enhancing of food products with macro- and micro-nutrients.
6. Biologically active food supplements on the basis of:
- albumen, amino-acids and their components;
  - essence lipids (vegetable oils, cod-liver oil);
  - carbohydrates and sugars, honey, syrups, etc.;
  - food fiber;
  - pure substances of macro- and micro-nutrients, biologically active substances or their concentrates with the use of various fillings;
  - natural minerals, including mumie;
  - food and medicinal plants, including flower pollen;
  - meat and milk materials, by-products, arthropoda, amphibia, bee-keeping products;
  - fish, sea invertebrates, crustacea, mollusca, etc.;
  - vegetable organisms of the sea;
  - pro-biotic micro-organisms;
  - unicellular alga;
  - yeast.
7. Food-stuffs made of genetically modified materials.

8. Food-stuffs made with the application of new technologies and/or of materials and other components that have never been used for such purposes before.
9. Materials and products that come in contact with food-stuffs:
  - raw polymer materials for production of articles that come into contact with food-stuffs;
  - steel, metall, and alloys
  - additives (anti-oxidants; stabilizers; plastifires, dye-stuffs, fillings) added to the raw material;
  - packing (including sealing) materials and ready-to-use packing articles;
  - articles for feeding infants;
  - plates, kitchen-ware, spoons, forks, etc.
  - lacquers, paints and other materials used to cover articles that come into contact with food-stuffs;
  - pressurizers, plastisols;
  - rubber and rubber articles;
  - domestic appliances (including electrical);
  - technical equipment and parts of technical equipment.
10. Perfumes and cosmetic products:
  - special cosmetic means (creams, face packs, pilling, balsams for hair) intended for professional use at cosmetic saloons and beauty shops, hairdressers', etc.;
  - special cosmetic products (artificial tan creams, skin whitening means, means for making pictures on the skin without injecting dyes), aromatic cosmetic products for genitals;
  - means of individual protection from impact of harmful factors (ointments, creams, pastes, etc.) for use in a workshop;
  - perfumes and cosmetic products for children;
  - hair dyes (except for temporary colorants (shampoos));
  - products for permanent wave.
11. Means for dental care:
  - fluorine-containing dental care products, in which the mass share of fluorine does not exceed 0.15 per cent;
  - teeth-whitening products containing 0.1 per cent. hydrogen peroxide;
  - medicinal / prophylactic tooth pastes for special use with pH 4.5 - 5.5;
  - dying tablets for revealing spots (thin coating) on the teeth;
  - chewing gum (medicinal / prophylactic).
12. Tobacco products, including source materials, supplementary materials and accessories
  - tobacco;
  - cigarettes;
  - cigarellas;
  - Russian cigarettes;
  - Other products made of tobacco or its substitutes, including other industrially produced tobacco and industrially produced tobacco substitutes, smoking and chewing tobacco;
  - Supplementary materials: sauces, aromatizers, flavoring, softeners, cigarette paper, essences for tobacco articles, foils, paste-board;

- Cigarette-holders;
- Filters;
- Tobacco-pipes.